

"Designated Original"



HITACHI

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18 March 2011

Ms. Michele M. Sampson, Sr. Project Manager
Licensing Branch
Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-001

ATTN: Document Control Desk

Copy to:

Associate Administrator for Hazardous Material Safety
Pipeline and Hazardous Materials Safety Administration
U.S. Department of Transportation
1200 New Jersey Avenue, S.E.
Washington, D.C. 20590-0001

Attn: Special Permits, PHH-31

Ltr. No. DRK-2011-07

Subject: Application for Extension of Authorization for Limited Shipments in the
Model No. 5979 Package, Certificate of Compliance No. 5979

- References:
- 1) NRC Letter to D.R. Krause, GEH, "Authorization for Limited Shipments in the Model No. 5979 Package, Certificate of Compliance No. 5979", Dated November 19, 2010.
 - 2) NRC Letter to B.A. Robnett, AOS, "Authorization for Limited Shipments in the Model No. 5979 Package, Certificate of Compliance No. 5979", Dated February 25, 2011.

Dear Ms. Sampson:

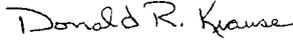
GE - Hitachi Nuclear Energy Americas, LLC ("GEH") with operations at the Vallecitos Nuclear Center (VNC), Sunol, California respectfully request authorization for continued limited shipments utilizing the expired Model 5979 Type B Package, owned by Alpha-Omega Services, Inc. ("AOS"). The previous authorization expired on February 28, 2011.¹ Attached please find GEH's submittal regarding the subject request.

GEH is aware AOS has been granted an amended authorization for the continued limited use of the 5979 Packages from March 1, 2011 through October 31, 2011, and that the authorization applies for a maximum of 27 Cobalt-60 (Co-60) sealed source shipments.² AOS is fully aware of and supports GEH's filing for an amended authorization for the continued limited use of the 5979 Package.

MMS524

Should the Department have any questions regarding this application, or additional information is required, please contact me or our Technical Contact Mr. Carlos Martinez at (925) 862-4481 or via e-mail at carlos1.martinez@ge.com.

Sincerely,



Donald R. Krause
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Nuclear Energy, ou=Vallecitos Nuclear
Center,
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2011.03.18 16:40:34 -07'00'

Donald R. Krause
Mgr., Regulatory Compliance & EHS

Attachment: Supplemental Information: Model No. 5979

Docket No. 71-5979
TAC No. L24503

cc: Troy Hedger (AOS)
Gaby Francis (GEH)
Andrew Langston (GNF-A)
Carlos Martinez (GEH)
Michael Schrag (GEH)
David Turner (GEH)

Supplemental Information
Model No. 5979
Certificate of Compliance No. 5979
Docket No. 71-5979; TAC No. L24503

- 1 *Identification of Shipments: (a) Number of shipments; (b) number of packages per shipment; (c) packaging serial numbers; (d) package contents; (e) end use of the radioactive material; (f) shipment origin and destination; (g) mode; (h) general timeframe (e.g., first quarter 2009); and (i) date last shipment will be completed.*
- (a) GEH's current application is for a maximum of twenty-five (25) shipments, using the Model 5979 Package, from March 1, 2011 through October 31, 2011.
 - (b) Each shipment shall be accomplished using one (1) Model 5979 Package.
 - (c) GEH proposes to make use of Model 5979 Package, Serial Numbers AOS-I, and AOS-II Cask/IIIA Overpack and Pallet.
 - (d) GEH proposes to transport Cobalt-60 (Co-60) as sealed sources that meet the requirements of Special form radioactive material. Each shipment shall consist of 192 or 201 individual Co-60 sources, with a nominal activity of 1.1TBq (30 Ci) per source.
 - (e) The proposed shipments shall be for the purpose of delivering Co-60 sealed sources for installation into domestic Gamma-Knife medical units or recovery of spent, used Co-60 sealed sources from an existing Gamma-Knife unit. Said sources are used in the treatment of brain ailments.
 - (f) As fabricator of the Co-60 sources, shipments shall originate at GEH's Vallecitos Nuclear Center (VNC), Sunol, California, with GEH as the "shipper of record". The shipments' destinations are domestic medical institutions identified by Elekta Instrument AB, manufacturer of the Gamma Knife unit. Presently, the majority of the delivery sites have not been identified to GEH due to pending contractual agreements between Elekta Instrument AB and the medical institutions and/or the issuance of sites' radioactive material license. Recovery spent source shipments shall originate at the medical institution for shipment to GEH's VNC, with GEH as the "shipper of record".
 - (g) All shipments shall be accomplished by truck as "Exclusive-Use" and are subject to security measures as defined in NRC Order EA-05-006 for Radioactive Materials Quantities of Concern (RAMQC).
 - (h) GEH is aware Alpha-Omega Services Inc. ("AOS"), owner of the Model 5979 Packages, has been granted an amended authorization for the limited continued use of the 5979 Packages, Serial Number AOS-I and AOS-II/IIIA, from March 1, 2011 through October 31, 2011, and that the authorization applies for a maximum of 27 Co-60 shipments. AOS is aware of and supports GEH's filing for up to 25 shipments using the 5979 Package from March 1, 2011 through October 31, 2011. The exact shipment schedule is unknown at this time, as noted in Paragraph (f) above.
 - (i) Under this application, the last proposed shipment shall be completed on or before October 31, 2011.
- 2 *Reasons for Requesting Extended Use. Justification for extending the use of expiring packages must describe why acquiring replacement packages is not practical and why shipments cannot be made before the October 1, 2008, expiration date. The justification must demonstrate that: (a) there are no alternative domestically approved packages available; (b) the contents cannot be reconfigured such that transport can be conducted in accordance with the regulations; and (c) the transport schedule cannot be adjusted so as to be conducted in*

accordance with the regulations. The justification must also describe any good-faith efforts to acquire replacement packages that meet the current package performance requirements, including a detailed description of past activities and the current status of acquiring replacement packages. In addition, any adverse impacts that will result if the shipment is not conducted should be fully described.

Not only is the Model 5979 Type B Package used to transport the Co-60 sources to the medical institutions, it is physically "docked" to the Gamma-Knife medical unit upon delivery, by means of a "loading machine" specifically designed to interface with the Model 5979 Package. Without the availability of the Model 5979 Packages, the medical treatment of brain cancer patients could be disrupted or completely stopped. Domestic medical institutions and patients would then be forced to rely solely upon foreign produced Co-60 sources transported into the U.S. by foreign packages, namely the Croft Type B Package, Certificate USA/0337/B(U)-96. Most domestic packages cannot be coupled to the Gamma Knife devise without considerable design efforts for source loading and unloading operations. In addition, using foreign vendors will severely impact domestic chain suppliers economically.

The replacement Package for the Model 5979, the AOS-100 (a Type B Package within the AOS Transport Packaging System), has been under development since 2005. On September 30, 2010, Revision D of the Safety Analysis Report was submitted. NRC design and licensing approval is expected in 2011 and the first package ready-for-use is anticipated 6-9 months thereafter.

- 3 *Safety Justification for Continued Use and Proposed Compensatory Measures. Since the expiring package designs may lack safety enhancements included in newer designs, the request must include a safety justification for continued use and a description of compensatory measures that will be used to provide an equivalent level of safety. Examples of compensatory measures that may be considered are: (a) special package inspections, tests, or determinations that ensure that the packaging is in unimpaired physical condition; (b) transport by exclusive use; (c) transport during time of low road usage; and (d) accompaniment of shipment by escort equipped to effect a recovery in an emergency situation or in case of a transportation accident.*

AOS has more than three decades of experience safely operating and maintaining the 5979 Packages, and it is GEH's understanding that AOS has experienced no containment, shielding, thermal or structural problems with the use of these packages during the past three decades. The Model 5979 Packages are operated and maintained under AOS Quality Program PR9000, approved by the NRC under Docket No. 71-0086, with an expiration date of July 31, 2019.

GEH shall operate the AOS 5979 Type B Packages in accordance with the Quality Assurance Program Approval for Radioactive Material Packages, No. 0170, approved by the NRC under Docket No. 71-0170. Further, GEH shall continue to adhere to and execute AOS's Model 5979 Container Operating Procedure, PR9100, in preparation for shipment and shall maintain copies on file of all pertinent documents associated with the Model 5979 Package.

Please note that GEH does not request any changes to the 5979 Package authorized contents listing, and that GEH will observe all operating and maintenance procedures on file with the NRC through the extended period. Further, GEH understands that this request will not be considered a form of certificate renewal, either under 10 CFR 71.38 or any other NRC regulation.

The applicable NRC certificate for the Model 5979 Package restricts the maximum quantity of Co-60 to 255 TBq (7,000 Ci) and 110 watts decay heat per package. The proposed GEH Co-60 shipments, using the Model 5979 Packages, are well below the aforementioned limits; the proposed Co-60 shipment activity are nominally 220 TBq (6,000 Ci), with a maximum (permissible Gamma Knife) activity of 240 TBq (6,600 Ci). Further, to ensure package safety during transport, all GEH shipments shall be planned and executed in accordance with NRC Order EA-05-006. The shipment shall be subject to continuous and active monitoring enroute.

- 4 *A Plan and Schedule to Acquire Replacement Packages or Complete Necessary Shipments. Details about the planned acquisition of replacement packages must be provided, along with key milestones, and proposed implementation dates, unless the licensee can show why acquiring a replacement package is not practical and why shipments cannot be made before the October 1, 2008, expiration date.*

In February 2005, AOS entered into a contract with GEH to develop a Type B Transport Packaging System, in accordance with the provisions of 10 CFR Part 71, to replace the Model 5979. The application for the Certificate of Compliance was submitted by AOS to the NRC in October 2007, and supplemented November 2007, under Docket No. 71-9316. In a conference call between AOS and the NRC on April 7, 2008, the NRC staff informed AOS of major technical deficiencies found in the application. On April 29, 2008, AOS informed the NRC staff, by letter, of its withdrawal of the AOS Transport Packaging System application, and intent to re-submit the application upon revising it to address the open technical issues identified by the NRC staff.

Revision B of the SAR was submitted by AOS to the NRC in September 2009. AOS received a Request for Supplemental Information (RSI) in July 2009. Revision C of the SAR and responses to the July 2009 RSI's was submitted to the NRC on September 2009. AOS then received Request for Additional Information (RAI) in December 2009. Due to the number and extent of the RAI's, the RAI responses and Revision D of the SAR was submitted on September 30, 2010. AOS estimates that it will be granted the certificate of compliance in calendar year 2011 and that the first AOS-100 package ready-for-use will be approximately 6-9 months later.

§ 107.109 - Application for Renewal
Model 100, Certificate of Compliance No. 5926

- (a) *Each application for renewal of a special permit or renewal of party status to a special permit must-*
 - (1)(i) *Be submitted in duplicate to: Associate Administrator for Hazardous Materials Safety (Attention: Special Permits, PHH-31), Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001;*
 - (1)(ii) *Be submitted in duplicate with any attached supporting documentation by facsimile (fax) to: (202) 366-3753 or (202) 366-3308; or*
 - (1)(iii) *Be submitted by electronic mail (e-mail) to: Specialpermits@dot.gov. Electronic submissions need not be submitted in duplicate;*

GEH's submittal will be made via electronic mail to *Specialpermits@dot.gov*.

- (2) *Identify by number the special permit for which renewal is requested;*

The special permit in question is DOT-SP 14772, associated with the Model 100 Type B Package, Certificate of Compliance No. 5926. GEH's current Special Permit is scheduled to expire on March 31, 2011.

- (3) *State the name, street and mailing addresses, e-mail address (if available), US DOT Registration number (if applicable), and telephone number of the applicant. If the applicant is not an individual, also state the name, street and mailing addresses, e-mail address (if available), and telephone number of an individual designated as an agent of the applicant for all purposes related to the application. In addition, each applicant for renewal of party status must state why party status to the special permit is needed and must submit a certification of understanding of the provisions of the special permit to which party status is being requested;*

Attached please find GEH's justification for renewal of party status to the special permit as documented in GEH's application to the NRC for extension of the authorization for limited continued use of the Model 100 Package through December 30, 2011. It is understood Party Status and extension of the Special Permit is subject to all conditions set forth in the pending NRC authorization for limited shipments in the Model 100 Package and that the Special Permit will not expire until final administrative action on the timely filed application for renewal of Party Status has been taken by the Department, by attaching a copy of GEH's dated, timely renewal request to the Special Permit.

The "point of contact" for the subject application and required contact information is provided below.

GE Hitachi Nuclear Energy Americas, LLC
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6705 Vallecitos Rd
Sunol, CA 94586

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- (4) *Include either a certification by the applicant that the original application, as it may have been updated by any application for renewal, remains accurate and complete; or include an amendment to the previously submitted application as is necessary to update and assure the accuracy and completeness of the application, with certification by the applicant that the application as amended is accurate and complete; and*

GEH hereby certifies that the information provided in the original application (GEH letter DRK-2009-03, "Application for Party Status, Model No. 100 Package, Certificate No. 5926", dated January 27, 2009), as updated herein for renewal and extension, remains accurate and complete.

- (5) *Include a statement describing all relevant shipping and incident experience of which the applicant is aware in connection with the special permit since its issuance or most recent renewal. If the applicant is aware of no incidents, the applicant must so certify. When known to the applicant, the statement should indicate the approximate number of shipments made or packages shipped, as the case may be, and number of shipments or packages involved in any loss of contents, including loss by venting other than as authorized in subchapter C; and*

GEH hereby certifies that it safely accomplished five (5) Co-60 shipments to QSA Global, Inc. (Burlington, MA), using the Model 100 Package, Serial No. 107, without incident of any kind from March 2009 through December 2010. Further, GEH certifies that it accomplished one Mo-99 shipment using the Model 100 Package, Serial No. 102, without incident of any in January 2011, from Oak Ridge National Laboratory (ORNL, TN) to GEH, with GEH as the "shipper".

- (6) *When a Class 1 material is forbidden for transportation by aircraft, except under a special permit (see Columns 9A and 9B in the table in 49 CFR 172.101), include a certification by the applicant for renewal of party status to a special permit to transport such Class 1 material, on passenger-carrying or cargo-only aircraft with a maximum certificated takeoff weight of less than 12,500 pounds, that no person within the*

categories listed in 18 U.S.C. 842(i) will participate in the transportation of the Class 1 material.

GEH hereby certifies that is has not shipped nor plans to ship Class 1 material in the Model 100 Package, Serial Numbers 102 and 107. Further, all Co-60 and Mo-99 shipments in the Model 100 Package are to be accomplished overland as "Exclusive-Use", making use of a truck.